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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,188	02/28/2002	Steven L. Rose	P-PM 4978	8656

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EXAMINER

SAUNDERS, DAVID A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

087,188

Applicant(s)

ROSE et al

Examiner

J. SAUNDERS

Group/Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 11/5/04
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-13, 15-17, 19-21, 23-63, 65, 68-72, 74 is/are pending in the application.
Of the above claim(s) _____ is/are withdrawn from consideration.
- ☒ Claim(s) 1-13, 15-17, 19-21, 23-51, 53, 65, 68-71 is/are allowed.
- ☒ Claim(s) 52, 54-63, 72, 74 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s): _____
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

The amendment filed on 11/05/04 has been entered. Claims 1-13, 5-17, 19-21, 23-63, 65, 68-72 and 74 are pending and under examination.

The amendment has overcome the following bases of rejection stated in the Office action of 5/6/04:

All 112, first paragraph rejections.

All prior art rejections.

Claims 52, 72 and 74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 52 is confusing because it depends from claim 42, which refers to an "individual"; however, claim 52 states nothing about the "individual" in relation to the "population" recited.

Claim 72 is confusing because it does not indicate which of the values X1 and X2 is the higher; like considerations apply to Y1 and Y2 and to Z1 and Z2.

Claim 72 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: The steps employed in a dual optimization strategy, as set forth in Example II.

Specifically, if one were to assume that X2 is higher than X1 and like wise for Y2 and Y1 and for ^{Z2 and} Z1 and, then claim 72 has omitted an intermediate step in which a "primary analysis" using the X1, Y1, and Z1 values ("primary cut-offs") selects the individual as being "positive". The data is then "re-evaluated" using the X2, Y2 and Z2

values ("second set of cut-off values"); following this re-evaluation, the individual is re-classified as either "positive" or "indeterminant".

Without fully stating how each of X1 and X2, as well as Y1 and Y2 and also Z1 and Z2, are employed to determine the states of the patient, one is confused as to how all of the recited cut-off values are to be used. Applicant is referred to specification pages 102-103, from which the examiner has obtained the terms recited supra with quotation marks.

Claims 54-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 54 recites new matter by virtue of reciting, in the concluding paragraph, "up to 60% liver fibrosis prevalence" and "at least about 70% accuracy".

Applicant appears to have drawn the "up to 60%" prevalence value from the 59.3% prevalence value in Table 6; however "59.3% does not support "up to 60%", and the examiner does not find "up to 60%" recited anywhere in the discussion of the data presented in Table 6; also, the examiner finds no such recitation in any more generic descriptions of the invention at pages 33-35 and 39-44, wherein prevalence rates are disclosed.

Likewise, applicant considers "at least about 70% accuracy to be supported by the data in Table 6 showing specific "Acc," values ranging from 69.59% to 80.41%.

However nothing in the discussion of Table 6 recites an accuracy of "at least about 70%". Furthermore, at pages 42-44, wherein "accuracy" is discussed in a more generic sense, the examiner finds no recitation of an accuracy, of "at least about 70%" and not even any recitation of an accuracy of "70%". Even if there were such a recitation of "70%" accuracy it would not have been in conjunction with a prevalence of "up to 60%".

In summary regarding claim 54, the Examiner considers that the recitations of "up to 60%" and "at least about 70%" could have reasonably been deduced as generic recitations from the data presented in Table 6, had these recitations been originally recited. However, applicant did not originally choose to describe his invention in terms of a prevalence of "up to 60%" and an accuracy of "at least about 70%"; instead, applicant originally described his invention of claim 54 in terms of a population with an "up to 40% fibrosis prevalence" and an accuracy of 90%. Since applicant did not possess or enable this degree of accuracy from his originally presented data, he is now trying to rescue his invention by reciting new percentages of prevalence and of accuracy.

Additionally, even if the above stated rejections of "up to 60%" prevalence and "at least about 70% accuracy" were not new matter, claim 54 would still contain new matter. Original claim 54 and every description of the accuracy of the invention at pages 42-44 recited, not only percentages of prevalence and of accuracy but, also a specific percentage of individuals within the recited population that are diagnosed with recited accuracy. Since no percentage of such individuals is recited in claim 54, applicant is not claiming the invention in the manner originally described.

Applicant's urgings of 11/05/04 have been considered but are unconvincing.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Saunders whose telephone number is (571) 272-0849. The examiner can normally be reached on Monday to Thursday from 8 AM to 5:30 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1734

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/LR
February 16, 2005

David A Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~162~~ 1644